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No.

In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, forecloses a medical necessity defense to the Act's prohibition against manufacturing and distributing marijuana, a Schedule I controlled substance.

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PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the United States of America, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-11a)[1] is reported at 190 F.3d 1109. The May 13, 1998 memorandum and order of the district court (App. 41a-81a) is reported at 5 F. Supp. 2d 1086. The other opinions and orders of the district court (App. 12a-40a) are unreported.

[1] "App." refers to the separately bound appendix to the petition for a writ of certiorari.

JURISDICTION

The judgment of the court of appeals was entered on September 13, 1999. A petition for rehearing was denied on February 29, 2000 (App. 82a). On May 22, 2000, Justice O'Connor extended the time within which to file a petition for a writ of certiorari to and including June 28, 2000, and on June 19, 2000, Justice O'Connor further extended the time within which to file a petition to and including July 28, 2000. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, and Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761, are set forth at App. 83a-92a.

STATEMENT

1. On January 9, 1998, the United States filed suit seeking an injunction against six marijuana distributors and ten associated individuals, alleging that the defendants' ongoing distribution (and in some cases manufacture) of marijuana violated the Controlled Substances Act (CSA).[2] On May 19, 1998, the District Court for the Northern District of California issued a preliminary injunction prohibiting the Oakland Cannabis Buyers' Cooperative and its director (collectively OCBC) and other marijuana distributors from manufacturing and distributing marijuana. App. 39a-40a (order); 41a-81a

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[2] Many such groups formed in the wake of California's Compassionate Use Act, or Proposition 215, passed in November 1996, which purports to authorize the possession and use of marijuana for medical purposes upon a physician's recommendation. See Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d) (West 1999).

(memorandum opinion).[3] On May 21, 1998, OCBC violated the injunction by openly distributing marijuana to numerous persons. *Id.* at 21a-23a. On October 13, 1998, the district court issued an order finding OCBC in civil contempt. *Id.* at 20a-37a. On October 16, 1998, the district court issued an order denying OCBC's motion to modify the injunction to permit marijuana distribution to persons who, in OCBC's view, have a "medical necessity," *i.e.*, persons having a doctor's certificate stating that (1) the person suffers from a serious medical condition; (2) the person would suffer imminent harm if he does not have access to marijuana; (3) marijuana is necessary for treatment of the person's condition or would alleviate the condition or symptoms associated with it; and (4) there is no legal alternative for the effective treatment of the condition because alternative legal drugs are either ineffective or result in intolerable side effects. *Id.* at 19a (denying motion for modification); see also *id.* at 7a-8a, 28a-29a (describing proposed medical necessity defense).

2. In a per curiam opinion, the court of appeals reversed the district court's denial of the motion to modify the injunction to allow the use of marijuana based on asserted medical necessity. App. 1a-11a.[4] The

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[3] In addition to the imposition of criminal and civil penalties for violations of the CSA, see 21 U.S.C. 841-863 (1994 & Supp. IV 1998), the CSA gives district courts jurisdiction to enjoin violations of the Act, 21 U.S.C. 882(a).

[4] The court of appeals also held that it lacked jurisdiction over OCBC's appeal of the district court's denial of a motion to dismiss, App. 2a-5a, and that OCBC's appeal of the district court's order finding it in contempt was moot because the district court on October 30, 1998, vacated its contempt order after OCBC represented to the court that it would comply with the injunction, *id.* at 5a-7a. Those rulings are not at issue here.

court of appeals held that the district court, in construing its equitable power to issue an injunction, erred in not "tak[ing] into account a legally cognizable defense that likely would pertain in the circumstances." *Id.* at 8a. The court of appeals explained that it saw "no indication that the 'underlying substantive policy' of the [CSA] mandates a limitation on the district court's equitable powers" "to formulate appropriate relief when and if injunctions are sought." *Id.* at 9a (quoting *Northern Cheyenne Tribe* v. *Hodel*, 851 F.2d 1152, 1156 (9th Cir. 1988)).

The court of appeals further concluded that the district court abused its discretion in not considering what the court of appeals described as the "strong public interest in the availability of a doctor-prescribed treatment that would help ameliorate the condition and relieve the pain and suffering of a large group of persons with serious or fatal illness." App. 9a-10a. "Indeed," the court observed, "the City of Oakland has declared a public health emergency" in response to the district court's denial of OCBC's motion to modify the injunction to authorize it to distribute marijuana. *Id.* at 10a. The court also expressed the view that "[t]he evidence in the record is sufficient to justify the requested modification," and the court had "no doubt that the district court could have modified its injunction, had it determined to do so in the exercise of its equitable discretion." *Id.* at 10a. "[B]y contrast," the court continued, the government had identified no "interest it may have in blocking the distribution of cannabis to those with medical needs, relying exclusively on its general interest in enforcing statutes." *Id.* at 11a. The court of appeals therefore remanded the matter to the district court "to reconsider" OCBC's request for a modification of the injunction to allow OCBC to

distribute marijuana to persons who would satisfy OCBC's proposed test of medical necessity. *Ibid.*[5]

3. Following the Ninth Circuit's decision, on May 30, 2000, OCBC filed a motion with the district court to modify the district court's injunction entered on May 19, 1998. On July 17, 2000, the district court granted OCBC's motion. App. 12a-17a. The court explained:

> On remand the government has still not offered any evidence to rebut [OCBC's] evidence that cannabis is medically necessary for a group of seriously ill individuals. Instead, the government continues to press arguments which the Ninth Circuit rejected, including the argument that the Court must find that enjoining the distribution of cannabis to seriously ill individuals is in the public interest because Congress has prohibited such conduct in favor of the administrative process regulating the approval and distribution of drugs.

Id. at 13a. The court therefore stated that, "[a]s a result of the government's failure to offer any new evidence in opposition to [OCBC's] motion, and in light of the Ninth Circuit's opinion, the Court must conclude

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[5] On May 10, 2000, the Ninth Circuit issued an order vacating and remanding the district court's February 25, 1999, order dismissing the counterclaims for injunctive and declaratory relief sought by individual intervenors who alleged that the preliminary injunction violated their asserted substantive due process rights to use cannabis to alleviate their medical conditions. The court of appeals reasoned that, "[a]lthough the substantive claim of violation of Fifth Amendment rights that underlies plaintiffs' claim in this appeal differs from the defense of medical necessity upon which we ruled in the earlier appeal, the injunctive remedy involved in both appeals is similar." *United States* v. *Oakland Cannabis Buyers' Coop.*, No. 99-15838, 2000 WL 569509, at *1 (9th Cir.).

that modifying the injunction as requested is in the public interest" and that it would "exercise its equitable discretion to do so." *Ibid.*

The district court accordingly issued an amended preliminary injunction order, which reaffirmed that OCBC was preliminarily enjoined from manufacturing, distributing, or possessing marijuana with the intent to manufacture or distribute it, in violation of 21 U.S.C. 841(a)(1). App. 15a-16a. The district court further ordered, however, that

> [t]he foregoing injunction does not apply to the distribution of cannabis by [OCBC] to patient-members who (1) suffer from a serious medical condition, (2) will suffer imminent harm if the patient-member does not have access to cannabis, (3) need cannabis for the treatment of the patient-member's medical condition, or need cannabis to alleviate the medical condition or symptoms associated with the medical condition, and (4) have no reasonable legal alternative to cannabis for the effective treatment or alleviation of the patient-member's medical condition or symptoms associated with the medical condition because the patient-member has tried all other legal alternatives to cannabis and the alternatives have been ineffective in treating or alleviating the patient-member's medical condition or symptoms associated with the medical condition, or the alternatives result in side effects which the patient-member cannot reasonably tolerate.

Id. at 16a-17a.

On July 18, 2000, the district court denied the government's motion for a stay of the court's July 17, 2000, modification order pending appeal.

REASONS FOR GRANTING THE PETITION

The Ninth Circuit has held that medical necessity is a "legally cognizable defense" to a charge of distributing drugs in violation of the Controlled Substances Act. App. 8a. The court has further held that district courts have the "equitable discretion" to fashion an injunction to permit an organization to engage in the ongoing distribution of marijuana, wholly outside the strict controls imposed by the CSA, to individuals claiming a medical necessity for the drug. App. 10a.

The conclusion that a court may exempt certain persons or transactions from the operation of the CSA, based on the view of those persons or the court on whether marijuana has some medical utility, cannot be squared with the judgment Congress itself made in placing marijuana in Schedule I, which applies to substances that have been authoritatively found under the CSA to have a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1). Nor can the court of appeals' decision be squared with Congress's recent statutory declaration that it "continues to support the existing Federal legal process for determining the safety and efficacy of drugs and opposes efforts to circumvent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration." Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761. Congress has assigned to the Attorney General and the Secretary of Health and Human Services, under prescribed standards and administrative procedures set forth in the CSA, the responsibility to determine whether the

manufacture and distribution of marijuana and other drugs should be permitted for specified medical purposes. It has not left that determination to individual courts or juries—much less to private organizations like the Oakland Cannabis Buyers' Cooperative.

Whether asserted medical necessity exempts the distribution of marijuana (and other drugs) from strict controls under the CSA is an issue of exceptional and continuing importance. By sanctioning the prospective distribution of marijuana under a common law defense of necessity, the Ninth Circuit's holding flouts the provisions of the CSA banning the distribution of marijuana outside strictly controlled circumstances and undermines the enforcement of the federal drug laws. It also opens the way for producers, distributors, or users of other drugs and devices not approved by the FDA to invoke "medical necessity" as a defense to enforcement of the nation's health and safety laws. The court of appeals' decision therefore warrants this Court's review.

1. a. The court of appeals seriously erred in holding that medical necessity is a defense under the CSA, and in further holding that a district court has the equitable discretion to fashion an injunction that would permit the distribution of marijuana for medicinal purposes wholly outside the strict regulatory regime of the CSA. A common law defense of necessity is available only "when a real legislature would formally do the same under those circumstances." *United States* v. *Schoon*, 971 F.2d 193, 197 (9th Cir. 1991), cert. denied, 504 U.S. 990 (1992). See also 1 Walter LaFave & Austin W. Scott, Jr., *Substantive Criminal Law* § 5.4, at 629 (1986) ("The defense of necessity is available only in situations wherein the legislature has not itself, in its criminal

statute, made a determination of values. If it has done so, its decision governs.").

The text, structure, and purposes of the CSA all compel the conclusion that Congress expressly has rejected the notion that an individual who claims a medical necessity for marijuana is exempted from the Act's prohibitions on the manufacture, distribution, or dispensing of marijuana. The text of the CSA makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense'" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. 841(a)(1); see also *United States* v. *Moore*, 423 U.S. 122, 131, 135 (1975). Since the enactment of the CSA in 1970, marijuana has been classified as a Schedule I controlled substance, a classification which means that marijuana has been found to have a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1).

The CSA also establishes a closed system of distribution for Schedule I controlled substances. No physician or pharmacy may dispense a Schedule I controlled substance to any patient outside of a strictly controlled research project that has been registered with the Drug Enforcement Administration (DEA) and approved by the Food and Drug Administration (FDA). 21 U.S.C. 823(f); 21 C.F.R. 5.10(a)(9), 1301.18 and 1301.32; 28 C.F.R. 0.100(b). By contrast, physicians and pharmacies may lawfully distribute controlled substances in Schedules II through V consistent with their DEA registration. 21 U.S.C. 829. Even for substances listed in Schedules II through V, however, the Act does not allow the essentially unregulated manufacture and distribution that the Ninth Circuit has countenanced

for marijuana, a Schedule I controlled substance. See 21 U.S.C. 822-829.

In addition, the CSA establishes an exclusive set of statutory procedures under which controlled substances that have been placed in Schedule I (or any other schedule) may be transferred between, or removed from, the five schedules, based on changes in scientific knowledge. 21 U.S.C. 811(a). Pursuant to that process, "any interested party" who believes that medical, scientific, or other relevant data warrant transferring marijuana to a less restrictive schedule may petition the Administrator of the DEA to initiate a rulemaking proceeding to reschedule marijuana. 21 U.S.C. 811(a); 21 C.F.R. 1308.43. The Administrator, acting on behalf of the Attorney General, must refer any rescheduling petition to the Secretary of Health and Human Services for a medical and scientific evaluation, which is binding on the Administrator. 21 U.S.C. 811(b). Any party aggrieved by a final decision of the Administrator may seek review in the court of appeals. 21 U.S.C. 877; see, *e.g.*, *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (D.C. Cir. 1994) (upholding Administrator's decision declining to remove marijuana from the list of Schedule I controlled substances). Based on that framework, the courts of appeals uniformly have held that the statutory rescheduling process is the exclusive means by which to challenge marijuana's placement in Schedule I.[6]

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[6] *United States* v. *Burton*, 894 F.2d 188, 192 (6th Cir.), cert. denied, 498 U.S. 857 (1990); *United States* v. *Greene*, 892 F.2d 453, 455-456 (6th Cir. 1989), cert. denied, 495 U.S. 935 (1990); *United States* v. *Wables*, 731 F.2d 440, 450 (7th Cir. 1984); *United States* v. *Fogarty*, 692 F.2d 542, 548 (8th Cir. 1982), cert. denied, 460 U.S. 1040 (1983); *United States* v. *Middleton*, 690 F.2d 820, 823 (11th

Finally, in a statutory provision enacted in 1998 and entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE," Congress declared that:

> (1) certain drugs are listed on Schedule I of the Controlled Substances Act if they have a high potential for abuse, lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision;
>
> * * * * *
>
> (3) pursuant to section 401 of the Controlled Substances Act, it is illegal to manufacture, distribute, or dispense marijuana * * *;
>
> (4) pursuant to section 505 of the Federal Food, Drug and Cosmetic Act, before any drug can be approved as a medication in the United States, it must meet extensive scientific and medical standards established by the Food and Drug Administration to ensure it is safe and effective;
>
> (5) marijuana and other Schedule I drugs have not been approved by the Food and Drug Administration to treat any disease or condition;
>
> (6) the Federal Food, Drug and Cosmetic Act already prohibits the sale of any unapproved drug, including marijuana, that has not been proven safe and effective for medical purposes and grants the Food and Drug Administration the authority to enforce this prohibition through seizure and other civil action, as well as through criminal penalties;

Cir. 1982), cert. denied, 460 U.S. 1051 (1983); *United States* v. *Kiffer*, 477 F.2d 349, 357 (2d Cir.), cert. denied, 414 U.S. 831 (1973).

* * * * *

> (11) Congress continues to support the existing Federal legal process for determining the safety and efficacy of drugs and opposes efforts to circumvent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration.

Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761 (*reprinted at* App. 89a-92a).[7] That legislation reaffirms Congress's continuing adherence to the existing FDA drug-approval process, and its continuing opposition to any effort to allow the medicinal use of marijuana or other Schedule I controlled substances until they are proven safe and effective based on appropriate findings by the FDA. See, *e.g.*, *Accardi* v. *Pennsylvania R.R. Co.*, 383 U.S. 225, 229 (1966) (continuing purpose of Congress reflected in "sense of Congress" enactment); *Harris* v. *United States*, 359 U.S. 19, 22 n.8 (1959) (continuing purpose of Congress reflected in subsequently-enacted legislation).

Those provisions leave no doubt that, had Congress considered whether an individual claiming a medical need for marijuana could violate the CSA with impunity, Congress would have answered the question

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[7] The legislation was prompted by state initiatives around the country to legalize marijuana for medicinal uses. The provision's sponsor, Representative McCullom, explained that the provision "is important" because, *inter alia*, "[m]ore than 30 States and the District of Columbia have been targeted for possible medical marijuana initiatives," and that such initiatives "have already been passed in California and Arizona." 144 Cong. Rec. H7720 (daily ed. Sept. 15, 1998); see also 144 Cong. Rec. S10,666 (daily ed. Sept. 21, 1998).

with a resounding "no." Yet in recognizing the availability of a medical necessity defense, the court of appeals has sanctioned the use of marijuana for medicinal purposes. That decision is directly at odds with Congress's express finding that marijuana has "no currently accepted medical use." 21 U.S.C. 812(b)(1). It also is inconsistent with the exclusive procedures under the CSA for the removal of marijuana from the list of Schedule I controlled substances in order to allow its use for medical purposes under specified conditions. 21 U.S.C. 811; cf. *United States* v. *Bailey*, 444 U.S. 394, 410 (1980) (noting that a necessity defense is unavailable "if there was a reasonable, legal alternative to violating the law").

Finally, the recognition of a medical necessity defense runs counter to the absolute ban on the distribution of marijuana and other Schedule I controlled substances outside a DEA-registered and FDA-approved research project. 21 U.S.C. 823(f); see also 21 U.S.C. 841(a)(1) (making the distribution and dispensing of controlled substances unlawful "[e]xcept as authorized" by the CSA); *United States* v. *Moore*, 423 U.S. at 131. Indeed, the Ninth Circuit's decision permits the distribution of marijuana under judicial imprimatur without any of the stringent limitations that Congress placed on the manufacture and distribution of controlled substances, even those listed in Schedules II through V. The CSA and the governing regulations require manufacturers, distributors, and dispensers of controlled substances to register with the DEA, 21 U.S.C. 822(a), 823, 21 C.F.R. 1301, and to establish effective controls to guard against the theft and diversion of controlled substances, 21 C.F.R. 1301.71-1301.76; authorize the Attorney General to inspect a registrant's establishment, 21 U.S.C. 822(f),

880; require the Attorney General to determine production quotas for Schedule I and II controlled substances, 21 U.S.C. 826, 21 C.F.R. 1303; impose substantial record-keeping and reporting requirements on registrants, 21 U.S.C. 827, 21 C.F.R. 1304; disallow the distribution of Schedule I and II drugs except pursuant to an order form issued by the DEA, 21 U.S.C. 828, 21 C.F.R. 1305; and establish prescription requirements for the dispensing of controlled substances in Schedules II through V, 21 U.S.C. 829, 21 C.F.R. 1306. The Ninth Circuit's recognition of a medical necessity defense cannot be squared with Congress's considered judgment that the threat to public health and safety mandates a complete ban on the manufacture and distribution of controlled substances outside the express terms of the CSA.

In *United States* v. *Rutherford*, 442 U.S. 544 (1979), this Court considered an analogous issue and held that a claim of medical need for a drug cannot override Congress's judgment that the drug not be distributed absent a finding by the FDA under the statutory framework that the drug is generally recognized by experts as safe and effective. In *Rutherford*, a class of terminally ill cancer patients and their spouses brought suit to enjoin the government from interfering with the interstate shipment and sale of Laetrile, a drug that had not been approved by the FDA under the Food, Drug, and Cosmetic Act (FDCA). The district court granted the requested relief, and the Tenth Circuit affirmed, holding that the safety and effectiveness protections of the FDCA had no reasonable application to terminally ill cancer patients since those patients, by definition, would die of cancer regardless of their treatment. *Id.* at 548-549. The Court unanimously reversed. The Court rejected the Tenth Circuit's

determination that an exemption from the FDCA was justified because the safety and effectiveness standards could have no reasonable application to terminally ill cancer patients, explaining that, "[u]nder our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy. * * * Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference." *Id.* at 555, 559. The Court also reasoned that the FDCA "makes no special provision for drugs used to treat terminally ill patients," and that "[w]hen construing a statute so explicit in scope," it is incumbent upon courts to give it effect. *Id.* at 551.

The Court's holding and reasoning in *Rutherford* apply with equal force to the CSA, whose text, structure, and paramount policies evince Congress's intent to ban the distribution of marijuana, even for medicinal purposes. Indeed, every court to have considered the issue has rejected the invocation of a medical necessity defense under the CSA. See *United States* v. *Burton*, 894 F.2d 188, 191 (6th Cir.) (concluding the defense was not available because the defendant could have attempted to participate in a government-approved program to study the effects of marijuana on glaucoma sufferers), cert. denied, 498 U.S. 857 (1990); *United States* v. *Belknap*, No. 92-5363, 1993 WL 30375, at **2 (4th Cir. Feb. 10, 1993) (unpublished) (concluding that there was "no legal or factual basis" for a medical necessity defense to marijuana prosecution); *United States* v. *McWilliams*, No. CR 97-997(A)-GHK (C.D. Cal. Nov. 5, 1999), slip op. 2-3 ("Because Congress has already determined that there is no accepted medical use for marijuana, * * * we conclude as a matter of law that the medical necessity defense is not available

in this case."); *United States* v. *Lederer*, No. CR-97-558 GEB (E.D. Cal. May 21, 1999), slip op. 5-9 ("Since the weighing of values required for the defense of necessity has already been conducted by Congress' proscription of the very acts [the defendant] sought to legitimize through his assertion of the defense, [the defendant's] motion is denied."); *United States* v. *Diana*, No. CR-98-068-RHW (E.D. Wash. Sept. 21, 1998), slip op. 5 (rejecting medical necessity defense because "Congress was aware of the competing interests in cases such as Defendants' and addressed them"); *United States* v. *Allerheilgen*, No. 97-40090-01-DES, 1998 WL 918841 (D. Kan. Nov. 19, 1998) (same).[8]

b. In reaching the contrary holding that medical necessity is a "legally cognizable defense," the court of appeals did not attempt to reconcile a medical necessity defense with either the text of the CSA or the 1998 legislation disapproving any attempt to legalize marijuana for medicinal use outside the existing framework

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[8] State courts that have construed state drug laws are divided on whether a medical necessity defense is available in a marijuana prosecution under those laws. Eight state courts have held that the defense is unavailable. *State* v. *Poling*, No. 26658, 2000 WL 572334, *7-*8 (W. Va. May 8, 2000); *State* v. *Ownbey*, 996 P.2d 510 (Or. Ct. App. 2000); *State* v. *Williams*, 968 P.2d 26 (Wash. Ct. App. 1998), review denied, 984 P.2d 1034 (1999); *Murphy* v. *Commonwealth*, 521 S.E.2d 301, 302-303 (Va. Ct. App. 1999); *State* v. *Tate*, 505 A.2d 941, 946 (N.J. 1986); *State* v. *Cramer*, 851 P.2d 147, 149 (Ariz. Ct. App. 1992); *Kauffman* v. *State*, 620 So. 2d 90, 92-93 (Ala. Crim. App. 1992); *State* v. *Hanson*, 468 N.W.2d 77, 78 (Minn. Ct. App. 1991). By contrast, four state courts have recognized the availability of the defense. See *State* v. *Bachman*, 595 P.2d 287, 288 (Haw. 1979); *State* v. *Hastings*, 801 P.2d 563, 565 (Idaho 1990); *Jenks* v. *State*, 582 So. 2d 676, 678-679 (Fla. Dist. Ct. App.), review denied, 589 So. 2d 292 (1991); *State* v. *Christen*, 704 A.2d 335, 337 (Me. 1997).

of the CSA and the FDCA. Rather, the court of appeals explained that it saw "no indication that the 'underlying substantive policy' of the [CSA] mandates a limitation on the district court's equitable powers" "to formulate appropriate relief when and if injunctions are sought." App. 9a. The court of appeals took the view that the district court abused its discretion first in failing to consider what it deemed the "strong public interest" in the availability of marijuana for medicinal purposes, and second in finding that an injunction against marijuana distribution could not be supported by the government's "general interest in enforcing its statutes." *Id.* at 9a, 11a.

Those conclusions, however, cannot be reconciled with this Court's precedents concerning the limits of a district court's equitable discretion in fashioning an injunction. This Court has long held that a district court sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation." *Virginia Ry. Co.* v. *System Fed'n No. 40*, 300 U.S. 515, 551 (1937). Likewise, in *Hecht Co.* v. *Bowles*, 321 U.S. 321, 331 (1944), the Court held that, where injunctive relief is sought pursuant to a statutory mandate, a court's equitable discretion must reflect the "large objectives" of the statute, "[f]or the standards of the public interest, not the requirements of private litigation, measure the propriety and need for injunctive relief." This principle was reaffirmed in *TVA* v. *Hill*, 437 U.S. 153, 194 (1978), in which the Supreme Court held that, in examining whether to enter injunctive relief, a court must be mindful that

> it is * * * emphatically * * * the exclusive province of the Congress not only to formulate legislative policies and mandate programs and

> projects, but also to establish their relative priority for the Nation. Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is for the Executive to administer the laws and for the courts to enforce them when enforcement is sought.

See also *Miller* v. *French*, No. 99-224 (June 19, 2000), slip op. 11.

Those principles dictate the conclusion that a district court lacks the discretion, based on its own perception of the public interest and its own weighing of possible medical benefits against the potential for abuse, to craft an injunction under the CSA which exempts from the injunction's reach the distribution of marijuana for medicinal purposes. Congress already has considered the public interest, balanced the relevant medical and other considerations, and concluded that, unless and until the DEA removes marijuana from Schedule I, the drug has no "accepted medical use" and a "high potential for abuse" (21 U.S.C. 812(b)(1)) and may not be manufactured, distributed, or dispensed outside of a program of research approved by the FDA and conducted by a practitioner registered with the DEA (21 U.S.C. 841(a), 823(f)). The Ninth Circuit therefore plainly erred in holding that a district court has the equitable discretion to modify its injunction based on a claimed public interest in distributing marijuana to those who claim to have a medical need for it.

2. a. The issue of whether the CSA forecloses the availability of a medical necessity defense is one of exceptional and continuing importance. For the first time, a court of appeals has ruled that persons and entities may lawfully engage in the distribution of marijuana if, in their view, the recipients of the marijuana

medically need the drug. That holding flouts the CSA's ban on the distribution of Schedule I controlled substances unless the distributor is registered with the DEA and conducting research approved by the FDA. See 21 U.S.C. 823(f). The court of appeals' decision likewise circumvents the Act's exclusive provisions for drug approval and rescheduling of controlled substances. See 21 U.S.C. 811, 812. And the decision relegates to district courts and juries the power to determine whether illicit drugs can be used safely and effectively as medicine, even though Congress in the CSA placed such determinations within the province of the Attorney General and the Secretary of Health and Human Services. Thus, the Ninth Circuit's decision seriously undermines the administration and effectiveness of the CSA.

The decision is also significant because it threatens the government's ability to enforce the federal drug laws in the nine States within the Ninth Circuit, which comprises a population of nearly 50 million people. U.S. Dep't of Commerce, *Statistical Abstract of the United States* (1994). Indeed, the Ninth Circuit's sanctioning of the distribution of controlled substances in a manner that the CSA expressly prohibits creates incentives for drug manufacturers and distributors involved in a wide variety of offenses involving marijuana (and other Schedule I controlled substances, such as heroin or LSD) to invoke medical necessity as a defense to their alleged drug trafficking. The recognition of such a defense will introduce illegitimate collateral issues into drug prosecutions and will consume unnecessary judicial resources by distracting the trier of fact from the core issues of guilt or innocence of a particular crime as defined by Congress in the CSA.

For example, in a recent case prosecuted in the Eastern District of California, a motions panel of the Ninth Circuit reversed a district court's order denying bail pending appeal, holding that, in view of the Ninth Circuit's decision in this case, the defendant, a distributor of marijuana, was "entitled to bail pending appeal if he can demonstrate: 1) a likelihood that he was entitled to present a medical necessity defense at trial; and 2) his release does not pose a danger that he will distribute marijuana to people not falling within the class of individuals described in *OCBC*." *United States* v. *Smith*, No. 99-10447 (9th Cir. Feb. 3, 2000), slip op. 1-2.

The court of appeals' recognition of a medical necessity defense also takes on added significance in light of the fact that a number of States in the Ninth Circuit—Alaska, California, Hawaii, Oregon, and Washington—have enacted legislation sanctioning the use of marijuana for medicinal purposes. See Alaska Stat. §§ 17.37.010-17.37.080 & 11.71.090 (1999); Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d); Haw. S.B. 862, 20th Legis. (1999) (signed into law on July 12, 2000); Or. Rev. Stat. §§ 475.300-475.346 (1999); Wash. Rev. Code §§ 69.51.010-69.51.080 (1997).[9] In those States, there is therefore no state law that would independently bar

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[9] A medical marijuana ballot measure likewise was approved by voters in Maine in November 1999. Carey Goldberg, *Maine Mulls Medical Use for its Seized Marijuana*, N.Y. Times, Mar. 14, 2000 at Nat'l Desk. We have been informed by the DEA that medical marijuana initiatives are underway in Arizona, Nevada, Colorado, Iowa, Maryland, Massachusetts, Minnesota, New Hampshire, and New York. A majority of voters in the District of Columbia also approved a marijuana initiative in November 1998, but Congress blocked implementation of that initiative. See 145 Cong. Rec. H12,238 (daily ed. Nov. 17, 1999).

the distribution of marijuana in the circumstances that the Ninth Circuit has sanctioned. Thus, unless the CSA can be enforced with respect to that distribution, drug traffickers, acting under the guise of "medical necessity," will be able to manufacture and distribute marijuana with impunity, even though the CSA reflects Congress's deliberate judgment that marijuana shall not be used for medicinal purposes outside the specific confines of the Act itself.

Finally, the Ninth Circuit's decision threatens the government's more general ability to enforce the federal drug laws with respect to other illegal and unapproved drugs. As this Court recognized in *Rutherford*:

> It bears emphasis that although the Court of Appeals' ruling was limited to Laetrile, its reasoning cannot be so readily confined. To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked.

442 U.S. at 557-558. That reasoning is equally applicable in this case. Under the Ninth Circuit's analysis, there is no reason that a defendant charged with offenses involving other Schedule I controlled substances or unapproved drugs—such as Laetrile—would not similarly be able to raise the defense of "medical necessity." The Ninth Circuit's decision therefore could significantly undermine the enforcement of the federal drug laws and the FDA drug-approval process, a result patently at odds with the statutory framework

that Congress has enacted. The court of appeals' decision therefore warrants this Court's review.

b. No further proceedings in the lower courts are needed to clarify the issues presented or to render the case suitable for resolution by this Court. As explained above, the Ninth Circuit held: (a) that medical necessity is a "legally cognizable defense" to a marijuana prosecution or a suit for an injunction against marijuana distribution, App. 8a; (b) that OCBC had "identified a strong public interest in the availability of a doctor-prescribed treatment [of marijuana] that would help ameliorate the condition and relieve the pain and suffering of a large group of persons with serious or fatal illnesses," *id.* at 9a-10a; and (c) that the government, which had "rel[ied] exclusively on its general interest in enforcing its statutes," had identified no "interest * * * in blocking the distribution of marijuana to those with medical needs," *id.* at 11a. To be sure, the court of appeals did not order the injunction modified to permit the distribution of marijuana, but rather referred the case to the district court for a determination whether the injunction should be modified in that respect. On remand, however, the district court granted OCBC's request to modify the injunction, and did so "in light of the Ninth Circuit's opinion." *Id.* at 13a. Thus, no further factual development is needed for this Court to resolve the legal issues presented.

Moreover, there is no reason to await an appeal of the district court's modification order in order to clarify the question presented. Although the government has filed a notice of appeal from the district court's July 17, 2000, order modifying the injunction, there is no reason to believe that the Ninth Circuit panel, which has retained jurisdiction over any appeal, App. 11a, will revisit its

fundamental holding that medical necessity is a legally cognizable defense that justifies violating the CSA—especially since the Ninth Circuit declined to reconsider that holding on the government's petition for rehearing and rehearing en banc.

Finally, with respect to the circumstances of this case, the court of appeals has already determined that "[t]he evidence in the record is sufficient to justify the requested modification." App. 10a. Indeed, the court of appeals stated that it had "no doubt that the district court could have modified its injunction, had it determined to do so in the exercise of its equitable discretion." *Ibid.* Given the terms of the court of appeals' remand, and the district court's actual modification of the injunction, further proceedings are unlikely to assist this Court in its review of the basic legal issues presented. And at the same time, to postpone review of the Ninth Circuit's holding would only exacerbate its adverse consequences by encouraging broad disregard of the Controlled Substances Act and the unregulated distribution of marijuana, with the attendant serious potential for abuse Congress sought to prevent by placing marijuana in Schedule I under the Act.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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